K122642

Section 5. 510(k) Summary

OCT 2 6 2012

1. Administrative

Device Information	
Device Name:	ABL90 Flex
Common Name:	Blood gases and blood pH test system
Product Code:	CHL (JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX)
Registration Number:	21 CFR 862.1120
Classification:	Class II
Classification Panel:	Clinical Chemistry

Submitter	
Company Name:	Radiometer Medical ApS
ER Number:	3002807968
Address:	Aakandevej 21 2700 Broenshoej Denkmark
Phone:	+45 3827 3827
Fax:	+45 3827 2727

2. Description of Device Modification

The ABL90 FLEX is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO2 , pCO2, potassium, sodium, calcium, chloride, glucose, lactate, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO2Hb, FCOHb, F MetHb, FHHb and FHbF).
The implementation of the WiFi option allows wireless functionality for establishing network connectivity; all of which is supported by wired LAN connection in the existing application.

3. Intended Use

The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.

4. Substantial Equivalence

The ABL90 FLEX with the implementation of the WiFi option is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
K092686 ABL90 Flex, Radiometer Medical ApS (subsequent submissions: K111897, K120197)

Predicate: ABL90 Flex (K092682)	
Similarities	**Differences**
Intended Use The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.	Wireless LAN network connectivity utilizing standard technology and protocols provided and supported by the operating system (Windows XP Embedded). Currently this is provided by establishing cabled LAN connections.
Blood Gas Measurement pH, pO_2, pCO_2 by potentiometry	
Electrolyte Measurement cK^+, cNa^+, cCa^{2+}, cCl^- by potentiometry	
Metabolite Measurement cGlu, cLac by amperometry	
Oximetry Measurement ctHb, sO_2 FO_2Hb, FHHb, FCOHb, FMetHb, FHbF	
Hemoglobin Measurement Spectrophotometry	
Identical Performance Characteristics	
Two-Point liquid calibration	
Menu driven touch screen	
Software operating system Microsoft XPE	
Sample Introduction Aspiration	
Dimensions (length x width x depth)	
External Power Source 230/120 V mains	

5. Performance Data

No performance characteristics are affected by the change. The performance data submitted in the original submission (K092686) still apply.

6. Conclusion

The ABL90 FLEX with the modification described above is substantially equivalent in Intended Use, fundamental scientific technology, and characteristics to the predicate ABL90 Flex. For the implementation of the change design control principles (risk management, verification, validation) have been applied which indicated that the change is of no impact to the performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Radiometer Medical ApS
c/o Martin Gabler
Aakandevej 21
Denmark DK-2700

OCT 26 2012

Re: k122642
Trade Name: ABL90 Flex Analyzer
Regulation Number: 21 CFR §862.1120
Regulation Name: Blood gases and blood pH test system
Regulatory Class: Class II
Product Codes: CHL, CEM, CGA, CGZ, GHS, GKR, JFP, JGS, JIX, KHP, KQI, JJY
Dated: October 1, 2012
Received: October 3, 2012

Dear Mr. Gabler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Devices and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH'S Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-576-. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800 638-2041 or (301) 796-5680 or at its Internet address http://www.fda/gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122642

Device Name: ABL90 Flex Analyzer

Indications For Use:

The ABL90 FLEX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, and oximetry in heparinised whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order.

pH, pO_2 and pCO_2: pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa^+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration,inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa^{2+}): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl^-): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIR)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use

510(k) Number (if known): k122642

Device Name: ABL90 Flex Analyzer

Indications For Use:

Glucose (*c*Glu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (*c*tHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO_2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

***F*O_2Hb:** oxyhemoglobin as a fraction of total hemoglobin.

***F*COHb:** carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

***F*MetHb:** methemoglobin as a fraction of total hemoglobin.

***F*HHb:** reduced hemoglobin as a fraction of total hemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): FHbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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